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COVID-19 mRNA Vaccines: Lessons Learned from the Registrational Trials and Global Vaccination Campaign

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Abstract

[illegible]

Categories: [illegible]
Keywords: [illegible]

Introduction And Background

[illegible]

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Review

Revisiting the registrational trials

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Absolute risk and the "number needed to vaccinate (NNV)"

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Gender-reporting of harms and data integrity issues

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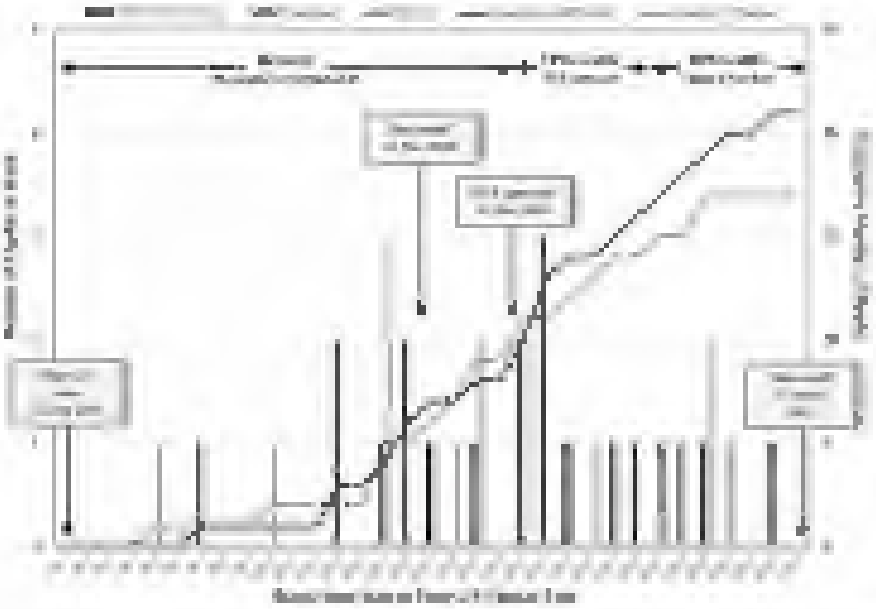

FIGURE 1: [illegible]

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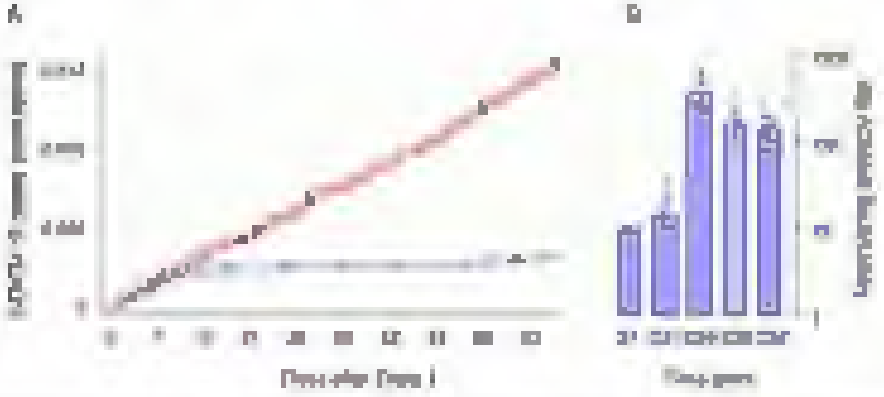

FIGURE 3: Graphs illustrating [illegible] in regarding of COVID-19 [illegible] and [illegible] independent [illegible]

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Minifying narratives, Museums of proximities

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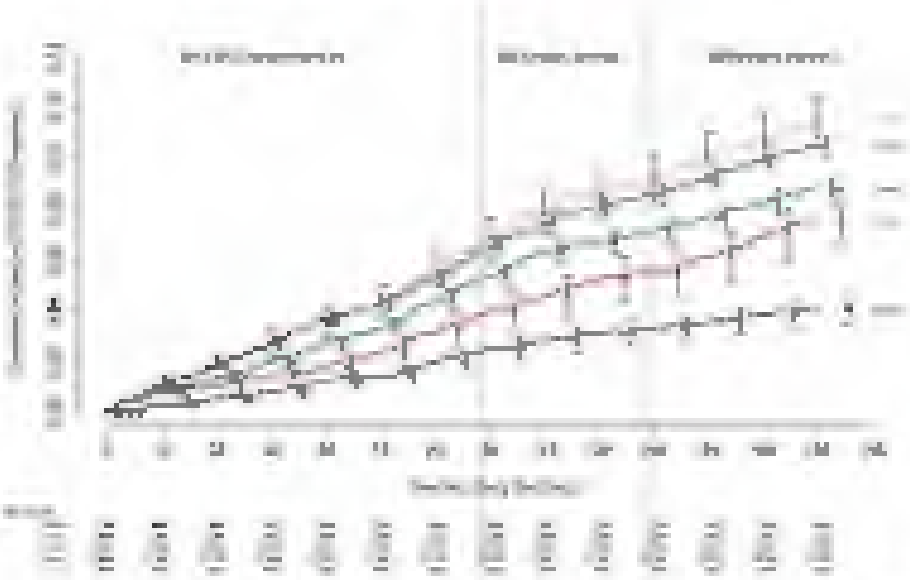

FIGURE 3 Cumulative Cases Among Unvaccinated COVID-19 Patients with Underlying Medical Conditions

Shaded lines show demonstrating COVID-19 incidence in unvaccinated individuals with the number of pre-existing medical conditions. The gray shaded vertical line marks the date when vaccinations were first administered in the United States.

Image Source: Shrestha et al., [illegible] https://doi.org/10.1371/journal.pone.0260544 Under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

FIGURE 4: Cleveland Clinic study showing increased COVID-19 cases for subjects [illegible] with mRNA vaccinations

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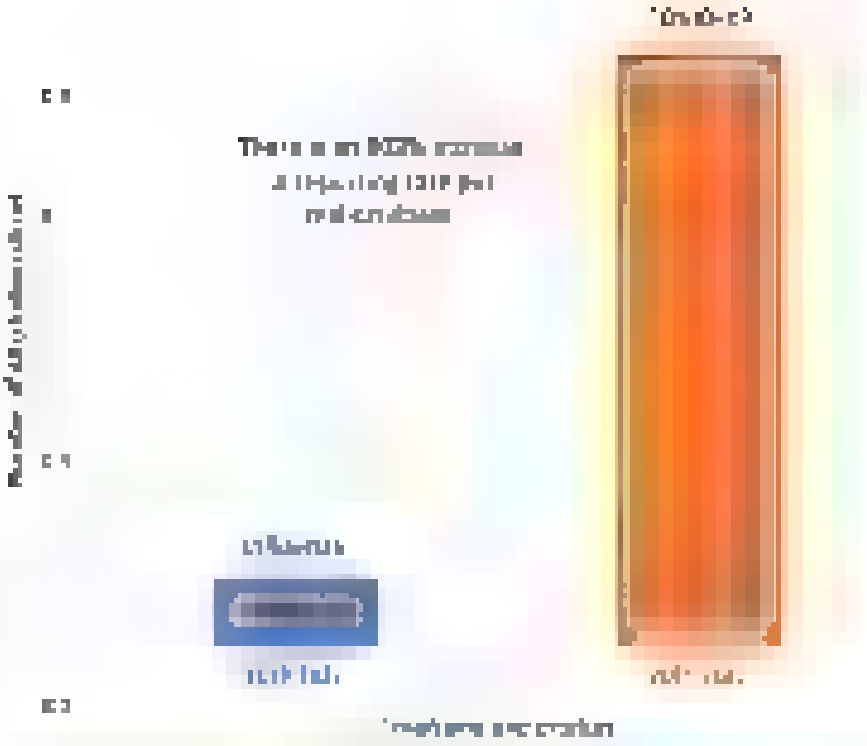

FIGURE 3 Weekly records of anaphylaxis cases per million doses of COVID-19 mRNA (BNT162b2) compared to influenza (2018–2021) vaccinations

Bars represent weekly case counts, grouped by vaccine type. Vertical axis: number of anaphylaxis cases reported. Horizontal axis: vaccination week. Dashed line: 95th percentile of influenza-vaccine weeks. Cases above the dashed line are marked in red. Source: VAERS, 2018–2021.

Mechanisms underlying ASIs

A recent review summarizes all the original articles and case reports published after COVID-19 vaccination and anaphylaxis, including 19 prospective studies, 3 retrospective studies, and more than 100 case reports. Most prospective studies enrolled healthcare workers and used active surveillance with standardized follow-up. Reported incidence varies by vaccine platform, dose, and population, but the pattern is consistent: anaphylaxis occurs within minutes to hours after injection, most often after the second dose, and is more common than expected from background rates.

The mRNA vaccines delivery lipid nanoparticles (LNPs) that contain polyethylene glycol (PEG) chains. Several lines of evidence implicate PEG-specific IgE and IgG4 antibodies in hypersensitivity reactions to these vaccines. Skin test positivity to PEG has been reported in patients with anaphylaxis, and serum PEG-specific antibodies have been detected in some cases. The same antibodies also bind to other PEG-containing products, including polyethylene glycol laxatives and injectable medications, which explains why a history of PEG allergy is a contraindication to mRNA vaccination in most guidelines.

Mast cell activation syndrome (MCAS) is a plausible mechanism in patients who react to vaccines but have no PEG allergy. Tryptase levels are rarely measured in acute anaphylaxis, but elevated tryptase in a patient with a documented reaction would support a diagnosis of MCAS and change the management plan. Pre-medication with antihistamines and corticosteroids is not routinely recommended, but it is sometimes used in patients who have had a prior reaction and need a second dose.

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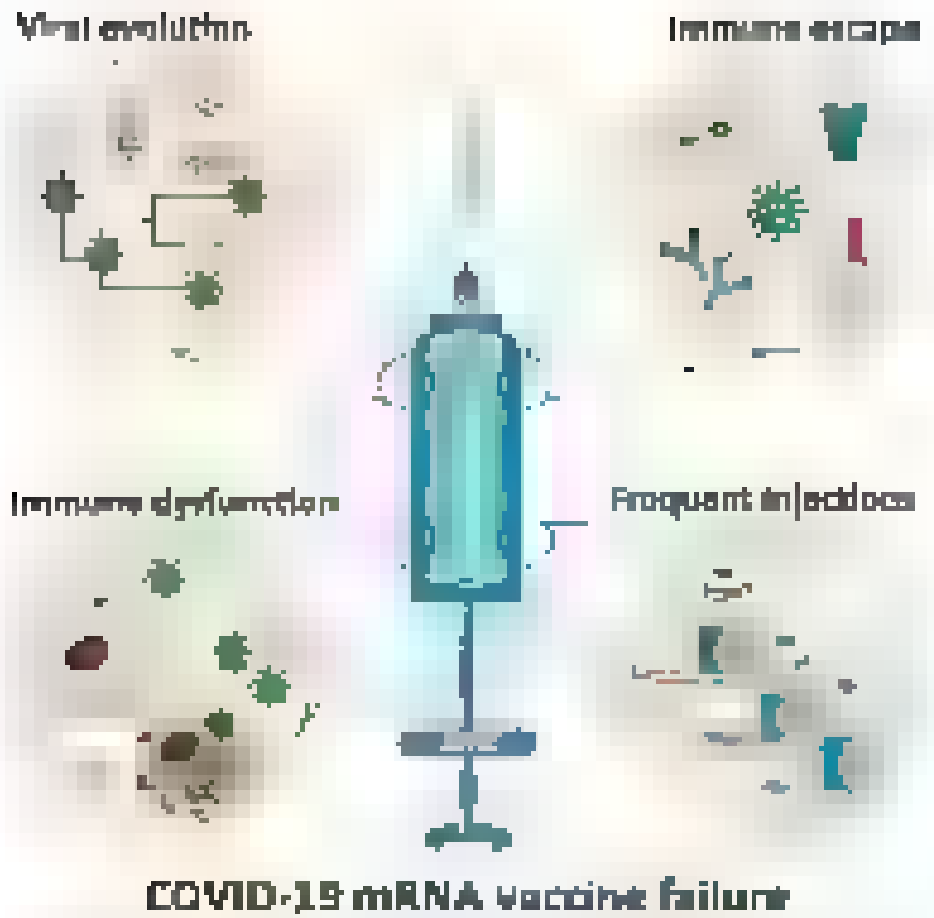

FIGURE 8: Factors contributing to COVID-19 mRNA vaccine inefficacy

Discussion

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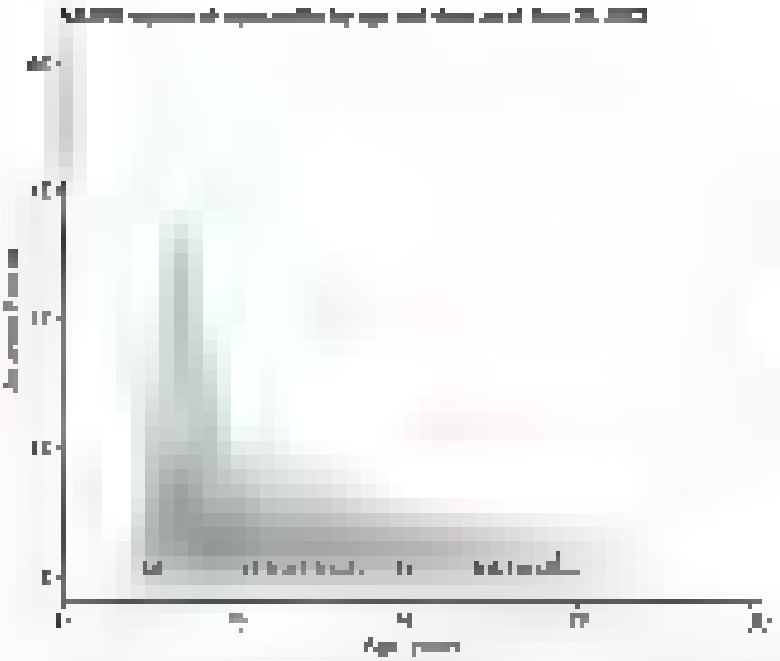

Table 11. Regulatory [illegible] by Quinella Investigator [illegible] as of Reporting Period [illegible], 2023, [illegible] by age and [illegible]

[illegible]	[illegible]	[illegible]	[illegible]
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Appendix [illegible]

FIGURE 8 Regressional fold for Pfizer, projected three-year mortality. By P the six-month Pfizer trial had continued, the risk difference would reach statistical significance at 24 months, with a 31% higher mortality risk in the vaccine group compared to the placebo group.

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Appendix 3

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[illegible]	[illegible]
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Conclusions

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Article [illegible]

Author Contributions

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Conclusions

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Acknowledgements

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References

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